

1 UNITED STATES DISTRICT COURT  
 2 DISTRICT OF NEVADA  
 3 BEFORE THE HONORABLE NANCY J. KOPPE, MAGISTRATE JUDGE  
 4 ---o0o---

4 Amarin Pharma, Inc., and :  
 5 Amarin Pharmaceuticals : No. 2:16-cv-2525-MMD-NJK  
 6 Ireland Limited, :  
 7 :  
 8 Plaintiff, :  
 9 : January 14, 2019  
 10 -vs- :  
 11 :  
 12 Hikma Pharmaceuticals USA, : United States District Court  
 13 Inc., et al., : 333 Las Vegas Blvd  
 14 : Las Vegas, Nevada  
 15 Defendant. :  
 16 \_\_\_\_\_:

17 TRANSCRIPT OF MOTIONS HEARING

18 A P P E A R A N C E S:

19 FOR THE PLAINTIFF: Christopher N. Sipes  
 20 Jason D. Smith  
 21 Michael Kennedy  
 22 Attorneys at Law

23 FOR THE DEFENDANT: Constance Huttner  
 24 Michael Rounds  
 25 Caroline Sun  
 Wayne Shaffer  
 Alan Clement  
 Eimeric Reig-Plessis  
 Attorneys at Law

**NJK/FTR: 011418@2:06pm**

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05:17:52 1 Las Vegas, Nevada, Monday, January 14, 2019, 2:06 p.m.

05:18:29 2 ---OoO---

05:19:00 3

05:19:04 4 THE CLERK: This is the time set for a motion  
05:19:06 5 hearing in the matter of Amarin Pharma, Incorporated, et al  
05:19:16 6 versus West-Ward Pharmaceuticals Corporation, et al. The case  
05:20:22 7 number is 2:16-cv-2525-MMD-NJK.

05:20:38 8 Beginning with plaintiff's counsel on the telephone  
05:20:43 9 line, please state your name for the record.

05:20:46 10 MR. SIPES: This is Christopher Sipes of  
05:21:46 11 Covington Burling for Amarin.

05:21:49 12 THE COURT: All right. Good afternoon,  
05:21:54 13 Mr. Sipes.

05:21:55 14 MR. SIPES: Good afternoon.

05:22:30 15 MR. KENNEDY: Michael Kennedy with Covington &  
05:22:32 16 Burling for Amarin.

05:22:34 17 THE COURT: Good afternoon, Mr. Kennedy.

05:23:15 18 MR. KENNEDY: Thank you.

05:23:24 19 THE WITNESS: Jason Smith with Santoro Whitmire,  
05:24:07 20 also on behalf of Amarin.

05:24:08 21 THE COURT: All right. Good afternoon,  
05:24:13 22 Mr. Smith.

05:24:16 23 MS. HUTTNER: This is Connie Huttner,  
05:24:31 24 representing the defendants, from Budd Lerner.

05:25:57 25 THE COURT: Good afternoon, Ms. Huttner.

05:26:06 1 MS. HUTTNER: Good afternoon, Your Honor.

05:26:18 2 MS. SUN: Caroline Sun from Budd Lerner, also  
05:26:26 3 representing Dr. Reddy's Lab.

05:27:56 4 THE COURT: Thank you. Good afternoon,  
05:27:59 5 Ms. Sun.

05:28:25 6 MR. ROUNDS: Michael Rounds from Brownstein  
05:28:47 7 Hyatt, Your Honor, representing the Dr. Reddy's defendants.  
05:29:02 8 Good afternoon to you.

05:29:04 9 THE COURT: All right. Good afternoon,  
05:29:09 10 Mr. Rounds.

05:29:49 11 MR. CLEMENT: Alan Clement from the Law Firm of  
05:30:54 12 Locke Lord on behalf of Hikma West-Ward.

05:33:15 13 THE COURT: Thank you. Good afternoon,  
05:33:18 14 Mr. Clement.

05:33:32 15 MR. REIG-PLESSIS: Eimeric Reig of Winston &  
05:34:35 16 Strong, also for defendants Hikma and West-Ward.

05:36:33 17 THE COURT: All right. Good afternoon,  
05:36:36 18 Mr. Reig.

05:36:37 19 I think that's everyone.

05:36:40 20 Is that correct?

05:37:03 21 MR. SHAFFER: One more, Your Honor.

05:37:08 22 THE COURT: Sorry.

05:37:10 23 MR. SHAFFER: This is Wayne Shaffer, also on  
05:37:23 24 behalf of Hikma, Laxalt & Nomura.

05:38:32 25 THE COURT: All right. Mr. Shaffer, good

05:38:35 1 afternoon. I didn't mean to leave you out.

05:38:38 2 All right. So, we're here today on two motions:  
05:39:00 3 The defendant's Emergency Motion to Modify the Scheduling  
05:39:06 4 Order, which is docket number 165; as well as the plaintiff's  
05:39:13 5 Motion to Amend the Preliminary Validity Contentions, docket  
05:40:00 6 number 168.

05:40:01 7 The Court is aware that the parties wanted to  
05:40:11 8 discuss the first motion at this hearing, but, really, they're  
05:40:22 9 kind of intertwined with each other, so if the parties want to  
05:40:29 10 argue both of them, we can address both of them today.

05:40:37 11 MR. SIPES: We're happy to do so, Your Honor.  
05:40:40 12 This is Christopher Sipes.

05:40:59 13 THE COURT: All right. So let's start with the  
05:41:04 14 motion to amend preliminary validity contentions. And,  
05:41:14 15 plaintiffs, that's your motion.

05:41:19 16 MR. SIPES: Your Honor, so what we had flagged  
05:41:23 17 in our original validity contentions back in July of 2017, the  
05:41:28 18 fact that we would be relying on the results of an ongoing  
05:41:33 19 clinical outcome trial, which was the cardiovascular effects  
05:41:52 20 of the drug product for Vascepa when is read out. The product  
05:43:26 21 read out this fall and the first publication of the results  
05:44:41 22 was on November 10th. It was announced at the American Heart  
05:44:52 23 Association conference in Chicago and published online in  
05:45:03 24 the New England Journal of Medicine. That was after the  
05:45:13 25 close of fact discovery, so we then put together supplemental

05:45:19 1 contentions and reached out to the defendants on December 7,  
05:45:32 2 raising the idea of supplementing at that time and we provided  
05:45:36 3 them, three days later, with the proposed supplement to our  
05:45:47 4 validity contentions.

05:46:21 5 The parties have known that REDUCE-IT was a part  
05:46:42 6 of this case since our contentions, and they deposed one of  
05:46:49 7 our 30(b)(6) witnesses, Dr. Ketchum on October 24th on the  
05:46:57 8 REDUCE-IT results. The top line results were announced, as I  
05:48:58 9 understand it, the data collection, the database, so to speak,  
05:49:08 10 was locked in September, was analyzed. The topline results  
05:49:22 11 were announced by the company in September 24. That was what  
05:49:29 12 they had then. They were then analyzing the results they  
05:49:58 13 were working with, you know, the outside researchers such as  
05:53:56 14 (unintelligible). And the first availability of the full  
05:54:17 15 analysis in the New England Journal was November 10, and there  
05:54:43 16 had been some follow-on publications that are also referenced  
05:55:01 17 in our supplemental contentions.

05:55:05 18 So, we believe we acted diligently. We flagged in  
05:55:17 19 our original contentions. There's no question defendants were  
05:55:32 20 aware of our reliance on REDUCE-IT. And pretty promptly upon  
05:55:55 21 the availability of the full analysis, we moved to supplement.  
05:56:00 22 We reached out to defendants to do so. We met and conferred  
05:56:04 23 with them. We provided them with our supplement. So, they  
05:56:09 24 had notice of our intent to supplement since December 7th.  
05:56:28 25 They've had the actual proposed supplement since

05:56:32 1 December 10th. And as they acknowledge in their own papers,  
05:56:38 2 they don't need to respond to this in their expert reports  
05:56:43 3 until March 11th in their second round.

05:56:47 4 So, I believe we've been diligent. We've shown good  
05:56:53 5 cause. REDUCE-IT is plainly relevant to this case. In fact  
05:57:06 6 during litigation, there own expert, you know, in pointing to  
05:57:17 7 the claims at issue in the case, which are for, among other  
05:57:36 8 things, to various affects on lipid parameters, said wall.  
06:06:42 9 For lipid parameters, you need the outcome evidence. Well,  
06:06:50 10 now, we have the outcome evidence, so we see this as plainly  
06:06:59 11 relevant, important to the case, and we've done everything we  
06:07:05 12 can to be diligent.

06:07:11 13 THE COURT: All right.

06:07:47 14 Defendants, whomever is --

06:07:52 15 MS. HUTTNER: Yes. It's Connie Huttner, Your  
06:07:59 16 Honor.

06:07:59 17 THE COURT: All right.

06:08:00 18 MS. HUTTNER: Let me, let me first address  
06:08:19 19 the motion to supplement. This study -- and just so you  
06:08:26 20 understand, this is a multi-year study involving -- I think  
06:08:46 21 it went on for seven years, involving thousands of patients.  
06:08:52 22 And it's been ongoing, I think, since 2011 or 2012. So, yes,  
06:09:04 23 they did put a placeholder in their, their original validity  
06:09:24 24 contentions, but the topline results of the study is of, uh --  
06:10:12 25 plaintiff's counsel conceded, were announced in September --

06:10:34 1 they were actually learned by the company, according to what  
06:10:40 2 counsel has told us, in mid September. We did attempt to  
06:10:45 3 depose their 30(b)(6) designee on the results of the study.  
06:10:51 4 We were told that the study had not been analyzed yet. And  
06:10:57 5 I understand that, at that point in time, the statistical  
06:11:11 6 analysis of the study results was ongoing.

06:11:28 7 They prepared an article for the New England Journal  
06:11:33 8 of Medicine, which was published on November 10th, but which  
06:11:37 9 had to, under the publication rules of that journal, had to  
06:11:45 10 have been submitted to them, probably, but late September or  
06:11:52 11 the first week in November at the latest. They could have a  
06:12:29 12 process of a topline results and produce the data in September  
06:12:35 13 prior to the close of discovery. They did not do that.

06:12:41 14 Similarly, they did not elect to provide us with  
06:12:44 15 any data or any New England Journal of Medicine article, or  
06:12:58 16 inform us that that article was going to be published until,  
06:13:03 17 uh, you know, we were contacted on December 7th, to see if we  
06:13:11 18 would consent to the supplementation. I believe the journal  
06:13:54 19 article, as it was published, was originally only available  
06:14:07 20 to subscribers of the journal. So it's not something, uh,  
06:14:13 21 that necessarily came to our attention.

06:14:15 22 In any event, Your Honor, the New England Journal of  
06:14:58 23 Medicine article only includes a small subset of data from the  
06:15:03 24 study. We had been told by plaintiff's counsel that the final  
06:15:38 25 study report, which will contain information that our experts

06:15:56 1 tell us they need to analyze, will study and determine whether  
06:16:01 2 it shows what it purports to show, will not be available  
06:16:07 3 until, according to what they told us, the end of the first  
06:16:10 4 quarter of this year; so, the end of March. And under the  
06:16:16 5 current schedule that we have, that would mean not only would  
06:16:26 6 we not see what they were prior submitting in their opening  
06:16:52 7 expert reports, but we would not see a final studying report  
06:17:03 8 prior to submitting our response to the expert reports, which  
06:17:21 9 is when, you know, they're saying that we need to deal with  
06:17:26 10 this data.

06:17:27 11 So, you know, what we're asking for here, Your  
06:17:30 12 Honor, is, really, fundamental fairness. They took almost two  
06:17:36 13 months to analyze the data to determine whether or not they  
06:17:39 14 even wanted to rely on it. It seems to us that we ought to be  
06:17:44 15 getting at least equal time to analyze the data on the other  
06:17:49 16 side, particularly since we don't have access, as they do, to  
06:17:54 17 investigators who were involved in this study. And one of  
06:18:01 18 their experts was one of the principal investigators in this  
06:18:13 19 study.

06:18:14 20 So, our experts are going to need a chance to  
06:18:19 21 analyze the data. And in order to do that, they need either  
06:18:24 22 the data itself, or a copy of the final study report; or, if  
06:18:43 23 there's a reasonably complete draft, you know, that could be  
06:19:05 24 provided along the way. But without that, you know, we're  
06:19:15 25 pretty much just shooting in the dark because, as I said, the



06:19:25 1 New England Journal of Medicine article contains a small  
06:20:02 2 subset. It does not contain all of the analyses that I  
06:20:07 3 understand that they're planning to include in the final  
06:20:12 4 study report, or even some of the analyses that they've done  
06:20:21 5 since the publication date of New England Journal of Medicine  
06:20:40 6 article. And not ought we to get that material, Your Honor,  
06:21:15 7 but we ought to be able to depose someone, you know, to make  
06:21:19 8 sure that we have a complete understanding of what's been  
06:21:22 9 produced, just as we would have done, had they provided this  
06:21:35 10 information during the discovery period.

06:21:38 11 We took discovery on all of the so-called objective  
06:21:48 12 evidence, obviously, that they identified. As I said, we did  
06:22:26 13 try to take discovery on the REDUCE-IT study as well, but we  
06:23:04 14 were frustrated and weren't able to do that because the study  
06:23:20 15 results weren't yet available. So that's what we're asking  
06:23:31 16 for.

06:23:31 17 I don't believe they were diligent in amending their  
06:23:37 18 contentions. As we pointed out in our responsive brief, you  
06:23:54 19 know, they had issued, I think, a total of eight patents.  
06:24:12 20 The results of the REDUCE-IT study, those patents were filed  
06:24:16 21 and prosecuted and issued before the study was complete, so,  
06:24:32 22 obviously, we anticipated what the results of the study would  
06:24:49 23 be. They could have included a similar disclosure in their  
06:24:52 24 original validity contentions. They can amend it at anytime  
06:25:34 25 since filing the validity contentions to include what they

06:25:38 1 anticipated what those results would be, based on whatever  
06:25:56 2 (unintelligible) issue that they had during the study.

06:26:07 3 Now, obviously, that was a situation to enable them  
06:26:50 4 apply for patents. They could have, they could have apprised  
06:27:01 5 us of that and give us a chance to take discovery on that.  
06:27:05 6 And, they could have provided us with the results as they  
06:27:14 7 obtained them. But now where we are, and, you know, we're  
06:27:29 8 being asked to -- in fact, you know, for them to have an  
06:28:00 9 (unintelligible), you know they can take two months to analyze  
06:28:39 10 the study and results to see if it benefits their side, but  
06:28:59 11 they don't want to give us any time or change the current  
06:29:06 12 schedule to allow us, you know, to look at it from the  
06:29:11 13 defense's point of view.

06:29:14 14 The only prejudice that they've identified is the  
06:29:18 15 possibility that the Court will not be able to decide this  
06:29:21 16 case prior to the expiration of there's an automatic  
06:29:45 17 (unintelligible) stay here that expires in January of 2020.  
06:30:02 18 I'm -- you know, I would submit two things, Your Honor. One,  
06:30:13 19 under the current schedule, summary judgment motions are due  
06:30:19 20 in June. And to the extent that summary judgment motions  
06:30:31 21 are filed, the Court's schedule indicates that no trial date  
06:30:37 22 will be set until after the Court decides those motions and,  
06:30:44 23 obviously, you know, there's no guarantee that the Court will  
06:30:48 24 decide those motions prior to January; or, even if it does,  
06:31:50 25 that it will be able to set trial and then decide the case

06:31:54 1 prior to January, even if there were no change in the  
06:31:57 2 schedule. Neither defendant has an FDA approval at this  
06:32:03 3 point. You know, there's nothing -- I mean, it's completely  
06:32:37 4 speculative at this point as to what impact, if any, you know,  
06:32:48 5 extending the trial out a brief two months would, as far as  
06:32:54 6 setting -- extending the schedule by two months would have any  
06:33:06 7 impact. And, you know, I don't think that's enough prejudice  
06:33:11 8 to basically say you're not entitled to the time to look at  
06:33:17 9 this data and analyze it with their experts and take  
06:33:20 10 discovery.

06:33:29 11 THE COURT: All right.

06:33:32 12 All right. And regarding that motion to extend the  
06:33:38 13 discovery deadlines, what is the plaintiff's position?

06:33:42 14 MR. SIPES: Yes, Your Honor. This is  
06:33:44 15 Christopher Sipes again.

06:33:46 16 So, there's two points. One is the delay and then  
06:33:50 17 the other is the information they want. Let me start with the  
06:34:00 18 information, uh, they want, and then we can talk about the  
06:34:06 19 delay.

06:34:09 20 (Unintelligible) one, there is an acknowledgement  
06:34:43 21 that they say themselves when they deposed Dr. Ketchum  
06:34:55 22 October 24th, the analysis was not even then complete. So,  
06:35:20 23 clearly, the REDUCE-IT results were not available until very  
06:35:32 24 close to November 10th publication date.

06:35:46 25 In terms of the data, they have the publication,

06:35:53 1 meaning journal publication. We've, in addition, offered  
06:36:14 2 them the near final draft of the body of the clinical study  
06:36:29 3 report, which is the data and analysis being submitted, as I  
06:36:35 4 understand it, to FDA when its ultimately submitted to FDA,  
06:37:17 5 when the agency reopens, but also when all the final data is  
06:37:22 6 applied. And we've offered to give them that by the end of  
06:37:27 7 the month.

06:37:29 8           What they seem to now be asking is not even for  
06:37:34 9 that, but for all of the individual patient data, which they  
06:37:42 10 even disclaimed originally that in their papers. They said  
06:38:02 11 they would be fine with summaries or tabular data; that is,  
06:38:30 12 which should be the body of the report. So, it would be  
06:38:41 13 unbelievably burdensome. This is a more than 8,000 patient  
06:39:07 14 study over five years, so the database of individual patient  
06:39:28 15 data is enormous. And as you can imagine, there are a lot  
06:39:47 16 of issues with individual patient data, making it part of  
06:39:51 17 litigation. We don't understand in their papers that they're  
06:40:05 18 continuing to ask for that because they said themselves in  
06:40:14 19 their reply paper, uh, Document 173, that they would be fine  
06:40:20 20 with summaries or tabular data. So the body of the clinical  
06:40:26 21 study report, a draft that's available, then should satisfy  
06:40:46 22 any need for additional data.

06:40:49 23           I should point out here, Your Honor, that in general  
06:40:59 24 in these patent cases, people rely on publications. And here,  
06:41:04 25 we're talking about the New England Journal of Medicine, which

06:41:17 1 is, clearly, a reliable publication. You know, they're  
06:41:29 2 relying on lots of clinical trials where they just rely on  
06:41:37 3 the publication. They're not providing underlying study  
06:41:42 4 data; for example, what the JELIS study did. And it would be  
06:42:22 5 unbelievably burdensome to give them the database as enormous  
06:43:04 6 as the REDUCE-IT database.

06:43:13 7 And so in terms of the data and analysis that goes  
06:43:22 8 beyond the New England Journal, we can give them the draft of  
06:44:50 9 the clinical study report by the end of the month.

06:44:54 10 In terms of -- we've tried to meet and confer --  
06:45:07 11 your colleagues have cut that off -- to work out something,  
06:45:12 12 including potentially giving them extra time, but then this is  
06:45:33 13 not a case where it's going to be disposed upon dispositive  
06:45:39 14 motions. It's a bench trial case. We can respond to the  
06:46:05 15 delay that they're asking for by, at the back-end, you know,  
06:46:10 16 not having dispositive motions. The problem is, as they push  
06:46:16 17 it further and further back, all the risk is on our side  
06:46:21 18 because the stay on approval is in January of next year, 2020,  
06:46:37 19 and we need to get the case tried before then, you know,  
06:46:44 20 resolved before then, so that we can vindicate our patent  
06:48:14 21 rights before they can get final approval and potentially  
06:48:18 22 launch their product in derogation of our patent rights. We  
06:48:34 23 feel that they're asking for delay when they don't need it and  
06:48:42 24 the risk is all on our side. And they've acknowledged --  
06:48:56 25 their response on the REDUCE-IT is in the second line reports.

06:49:08 1 Even now, that's not due until March 11th.

06:49:13 2 So, yeah, we'll give them the clinical study report  
06:49:24 3 by at the end of the month and they'll have, you know, a  
06:49:27 4 month-and-a-half to analyze that for their second round  
06:49:32 5 reports.

06:49:37 6 MS. HUTTNER: Your Honor, if I may --

06:49:40 7 THE COURT: Yes.

06:49:42 8 MS. HUTTNER: -- respond briefly.

06:49:44 9 THE COURT: You may.

06:49:50 10 MS. HUTTNER: The offer to provide a near final  
06:49:55 11 draft, as Mr. Sipes put it, of the final study report was  
06:50:12 12 contingent on us agreeing to drop any right to move for  
06:50:17 13 summary judgment on the current schedule. So, you know,  
06:50:23 14 from our perspective, that was a non-offer. And the reason  
06:51:08 15 why it was a non-offer, from our perspective, is because  
06:51:12 16 there are, right now, a considerable number of claims that  
06:51:22 17 are being asserted by plaintiffs, but we do not believe that  
06:51:38 18 we infringed, and that those can be resolved on motion. It  
06:51:59 19 may be that plaintiffs drop some of those claims, or drop all  
06:52:06 20 of those claims. I don't know what they're going to do. But  
06:52:16 21 at the present time, it would be, you know, irresponsible for  
06:52:28 22 us to agree to give up the right to move for summary judgment,  
06:54:49 23 and certainly not as a condition of getting discovery that we  
06:54:53 24 should get as a matter of course. So, you know, that's where  
06:54:58 25 that went.

06:55:00 1 Mr. Sipes seems to be suggesting that he's willing  
06:55:12 2 to give it to us now and we would be happy to have whatever  
06:55:27 3 they want to produce as soon as they can produce it, but the  
06:55:49 4 point is that, you know, we need an opportunity to analyze  
06:56:01 5 what's written.

06:56:02 6 As far as the study data itself, I'm not sure why,  
06:56:21 7 you know, this is being perpetuated here. We've made it very  
06:56:28 8 clear we have no interest in patient HIPAA nor HIPAA sensitive  
06:57:07 9 data. We don't care about the identity of the patients.  
06:57:18 10 We're more than happy to work with them to try to narrow our  
06:57:24 11 request, but we've been unable to get from them even an index  
06:57:31 12 to what they anticipate having in what they call appendices to  
06:57:49 13 the study, which is, you know, where the actual data is going  
06:57:58 14 to be lodged, I gathered. But, we don't even have a list of  
06:58:08 15 what they claim to include to be able to say, you know, we  
06:58:19 16 need this or we want this or we don't want that or to work  
06:58:24 17 with them. You know, we've also told them we're happy to  
06:58:38 18 work with them, you know, to obtain information in tabular  
06:58:47 19 format because, frankly, we have no interest in getting a  
06:58:55 20 morass of data that, um, you know, is difficult and expensive  
06:59:10 21 to analyze. So for farther down the road, you know,  
06:59:46 22 they're doing an analysis that they're doing anyway to  
07:00:42 23 (unintelligible) for us, which is why we would like to get  
07:00:50 24 a copy of the final study report before we have to respond to  
07:00:55 25 whatever it is they're going to say about the REDUCE-IT study.

07:01:12 1 So, you know, that's really, you know, what's  
07:01:23 2 critical here. I mean, I -- they say that all the risk is on  
07:01:33 3 them, I'm not even sure what that means. I mean, we cannot  
07:01:40 4 launch without getting FDA approval. We don't have FDA  
07:01:48 5 approval. They will, you know, undoubtedly, win on the FDA  
07:02:12 6 approval, you know, when and if we even get it, at whatever  
07:02:42 7 point that is. They'll have ample opportunity, if we're not  
07:02:54 8 able to work something out, they'll have ample opportunity,  
07:03:00 9 you know, to move for injunctive relief, if need be, which  
07:03:12 10 it may never be needed because timing of (unintelligible)  
07:03:37 11 timing here is uncertain. The timing of the judge's review  
07:03:53 12 of summary judgment motions, assuming they're filed, is  
07:04:06 13 uncertain. And the timing of any trial date, even if the  
07:04:25 14 judge resolves the summary judgment motions is uncertain.  
07:04:29 15 And I think, you know, with the current schedule, I think the  
07:04:48 16 odds are probably against the judge deciding summary judgment  
07:04:53 17 motions, scheduling the trial, and deciding the trial before  
07:04:58 18 the, you know, the 30-month stay expires in January. But  
07:05:13 19 I don't want to leave you with the impression that once the  
07:05:50 20 30-month stay expires, that we're, you know, that we're on the  
07:06:08 21 market, you know, immediately. I mean, they'll be -- this  
07:06:28 22 will all get sorted out as, you know, we get closer to that  
07:06:32 23 point in time, both in terms of whether there's going to be  
07:06:36 24 summary judgment motions, what the Court's schedule is, and,  
07:06:47 25 you know, what the regulatory time frame is.



07:06:51 1 So, you know, there's no risk to them here. You  
07:06:54 2 know, I don't, I don't really see -- I mean, normally, the  
07:07:40 3 brand is the one that wants to extend things out as long as  
07:07:44 4 possible and, certainly, there have been many instances in the  
07:08:00 5 past where cases have been decided after the 30-month stay had  
07:08:05 6 ended, whether by agreement or because there was a regulatory  
07:08:18 7 approval or otherwise. And so there's nothing unusual or  
07:08:26 8 surprising there.

07:08:30 9 THE COURT: All right.

07:08:31 10 MR. SIPES: Your Honor, if I could just briefly.  
07:08:40 11 This is Christopher Sipes.

07:08:45 12 THE COURT: All right.

07:08:47 13 MR. SIPES: To be -- one, I'm not entirely sure  
07:08:57 14 now what data they're asking for, you know, whether they're  
07:09:02 15 fine with, you know, the summaries that are in the draft  
07:09:19 16 clinical study report, or whether they want individual patient  
07:09:27 17 data, which is more than 8,000 patients over five years is an  
07:09:39 18 enormous database. So, that, I just don't understand. If  
07:09:49 19 they're willing to have the summaries, then I think the draft  
07:09:59 20 clinical study report should be fine.

07:10:16 21 In terms of timing, it's true that there are cases  
07:10:20 22 that go on beyond the 30-month stay. In my experience, when  
07:10:25 23 that happens, the defendants agree not to launch without  
07:10:35 24 30 days notice, so that there's an opportunity for a  
07:10:39 25 preliminary injunction practice. What is otherwise being

07:10:47 1 suggested is that we're at risk with having to come in with a  
07:10:59 2 TRO if they suddenly get final approval. We don't think  
07:11:09 3 that's fair to us. We don't think that's fair to the Court.  
07:11:15 4 And we should have an opportunity to have an orderly process  
07:11:19 5 if the delay here means we're going to go beyond the 30-month  
07:11:25 6 stay.

07:11:32 7 MS. HUTTNER: And, Your Honor, I think that  
07:11:34 8 that's a discussion that we can have down the road. But, at  
07:11:40 9 the moment, you know, they have no guarantee that the case is  
07:11:52 10 going to get decided before the 30-month stay ends anyway.  
07:11:57 11 So, you know, as we get closer to that, to January 2020, when  
07:12:04 12 the stay expires, we can have all those discussions, if  
07:12:14 13 they're appropriate, at that time. But, right now, I think  
07:12:28 14 the issue is whether they're going to suffer some sort of  
07:12:36 15 prejudice if they schedule these out two months in order to  
07:12:53 16 give the time to review, you know, the final study results  
07:13:14 17 before we have to comment on them. You know, you're asking  
07:13:21 18 experts to put in an opinion, you know, whose professional  
07:13:30 19 opinion analyzing that study, and I don't think it's  
07:13:34 20 appropriate to do that with incomplete data. I reiterate  
07:13:46 21 again we're not looking for individual patient data, or would  
07:13:54 22 be -- you know, we had a long discussion. There was a call  
07:14:05 23 that we had to try to resolve this. I don't remember if it  
07:14:12 24 was last week or the week before. But, you know, we had a  
07:14:22 25 discussion at great length at that time trying to narrow

07:14:29 1 down -- you know, we explained to them what we were interested  
07:14:40 2 in and, uh, I don't know whether the draft that they're  
07:14:45 3 talking about includes that or not, but it's something that  
07:14:48 4 they were going to check on. And the response was, you know,  
07:14:56 5 that they sent back was equivocal as to what's going to be in  
07:15:10 6 the final study report.

07:15:13 7           So, you know, I'm happy to have a dialogue with  
07:15:17 8 them, you know, to try to narrow what we want. We're not  
07:15:25 9 interested in getting a lot of data that would take us, you  
07:15:29 10 know, a lot of time and money to analyze. You know, so, you  
07:15:36 11 know, this is not a situation -- we're not looking, certainly  
07:15:53 12 not looking to invade anybody's HIPAA privacy. You know,  
07:16:05 13 we're not looking to get personal data. We're not looking to  
07:16:10 14 violate HIPAA here. We're just looking for the data that our  
07:16:15 15 experts are telling us that they need to analyze whether the  
07:16:21 16 results of the study in fact purport to show what they say it  
07:16:28 17 shows, and to analyze the nexus issue, uh, which, you know, as  
07:16:44 18 we explained in our reply brief, you know, we think that  
07:16:52 19 doesn't exist here. But, you know, that's really -- this, I  
07:16:57 20 think is a Red Herring that we're looking for individual  
07:17:07 21 patient data. We're not.

07:17:09 22           THE COURT: All right.

07:17:11 23           All right. The Court finds that -- I'm going to  
07:17:19 24 start with the later motion, the Motion to Amend the Validity  
07:17:24 25 Contentions. It's docket number 168. The Court finds that

07:17:43 1 the plaintiffs have been diligent and that there is good cause  
07:17:49 2 to amend those validity contention, so the Court is going to  
07:17:54 3 grant that motion.

07:18:08 4 The Court also finds, however, that granting that  
07:18:14 5 motion without providing an extension of the discovery  
07:18:20 6 deadlines to defendants would be prejudicial to the  
07:18:27 7 defendants. So, the Court is going to grant the Motion to  
07:18:31 8 Modify the Scheduling Order at docket number 165, and is  
07:18:39 9 going to -- there are proposed modification dates set forth  
07:18:46 10 on page 6 of that motion. The Court is going to order that  
07:20:09 11 those are the new deadlines.

07:20:12 12 Regarding the information about the patient data,  
07:20:18 13 whether it's summaries or what the discovery should be, first  
07:20:26 14 of all, that's not really briefed before the Court at this  
07:20:34 15 point. And secondly, it sounds as if the parties are,  
07:20:42 16 essentially, if not on the same page, very close to the same  
07:20:47 17 page regarding that information. So, the Court is going to  
07:20:52 18 defer ruling on that issue at this time. If the parties, of  
07:20:59 19 course, cannot agree, after meeting and conferring about this  
07:21:03 20 issue, then either or both of the parties can bring that issue  
07:21:09 21 before the Court.

07:21:11 22 Is there anything else on this -- oh, the second  
07:21:17 23 motion was docket number 165.

07:21:24 24 Is there any --

07:21:27 25 MR. CLEMENT: Your Honor, Alan Clement on behalf

07:21:30 1 of West-Ward Hikma.

07:21:39 2 THE COURT: Yes.

07:21:40 3 MR. CLEMENT: Just taking in conjunction with --  
07:22:42 4 when we set those dates out there, we were also asking for one  
07:22:52 5 7-hour deposition or, you know, depo or less, should we now  
07:23:12 6 need it, to take a deposition limited to the new information  
07:23:16 7 that plaintiffs provide.

07:23:19 8 THE COURT: Right. That request is granted as  
07:23:21 9 well.

07:23:23 10 MR. CLEMENT: Great. Thank you, Your Honor.

07:23:25 11 THE COURT: All right. Is there anything else  
07:23:27 12 on either of these matters.

07:23:30 13 MS. HUTTNER: Not from defendants, Your Honor.

07:23:32 14 MR. SIPES: No, Your Honor.

07:23:33 15 THE COURT: All right. Thank you, everyone.

07:23:36 16 MS. HUTTNER: Thank you.

07:23:39 17 MR. SIPES: Yes.

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19 (Court Adjourned.)

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I certify that the foregoing is a correct  
transcript from the record of proceedings  
in the above-entitled matter.

\s\ Kathryn M. French

January 16, 2019

KATHRYN M. FRENCH, RPR, CCR  
Official Reporter

DATE